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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,025	08/28/2001	Bryan Julien	300622002021	6462
25225	7590	08/12/2004	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

204

Office Action Summary

Application No.

09/942,025

Applicant(s)

JULIEN, BRYAN

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/12/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Alignments.

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DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (mailed on January 21, 2004), Applicants filed an election and amendment received on May 24, 2004. Said amendment cancelled Claims 1-3 and added new Claims 4-13. Thus, Claims 4-13 are pending in the instant Office action.

Election

2. Applicant's election without traverse of Group VII, Claim 1 relating to vectors comprising SEQ ID NO:12 or a portion thereof, in the reply filed on May 24, 2004 is acknowledged. The newly filed claims are all within the scope of the elected invention since they all require SEQ ID NO:12 or a PKS-domain-portion thereof. Claims 4-13 are pending and will be examined herein.

Priority

3. The instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/271,245 filed on February 15, 2001 and non-provisional Application No. 09/144,085 filed on August 31, 1998 as requested in the application data sheet.

The instant application is not granted the benefit of priority for the U.S. non-provisional Application 09/010,809 filed on January 22, 1998 as requested in the application data sheet because this application does not cite Julien, the sole inventor of the instant application, as a inventor (i.e., the applications do not have at least one inventor in common).

Information Disclosure Statement

4. The information disclosure statement filed on August 12, 2002 fails to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The following references were not considered for the reasons described below:

- a) References 30 and 32 are incomplete since they do not cite a date of publication.

All other documents in said Information Disclosure statement were considered as noted by the Examiner initials in the copy attached hereto.

Compliance with the Sequence Rules

5. Applicant filed a copy of the sequence listing in computer readable form and CD-ROM (in lieu of paper copy) on July 16, 2003 containing 27 sequences; said listing has been entered. The CD-ROM (in lieu of paper) copy of the sequence listing cannot be located; the Examiner requests that Applicant file an additional 2 copies in response to the instant Office action along with a statement of sameness to complete the record.

Objections to the Specification

6. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---DNA vector Encoding tmbA from the Polyketide Synthase Gene Cluster for the
Production of Tombamycin---

7. The amendment filed August 28, 2001 is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. Although the amendment was filed on the filing date of the instant application, said amendment is not referred to in the declaration and is, thus, considered an amendment and not an original part of the specification (see M.P.E.P. § 608.04(b)). The added material which is not supported by the original disclosure is as follows: the incorporation by reference of 60/271,245 that is not found in the originally filed specification. Applicant is required to cancel the new matter in the reply to this Office Action or to cite support for the entirety of the provisional application in the instant application as originally filed.

8. The specification is objected to for the term “tombamycin” as used to describe the structure in Figure 2 as well as the product of the enzymes encoded by the gene cluster disclosed as SEQ ID NO:1. Tombamycin is not a recognized compound name in the National Registry. The term “tombramycin”, while not being found in the National Registry, was found by the Examiner in a Google search with a limited number of hits, wherein said term appears to describe an antibiotic, which seems relevant since many polyketide synthase gene cluster encode proteins for the biosynthesis of antibiotics. However, clarification of the spelling and/or the nature of the compound is required.

Claim Rejections - 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 4-13 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The instant gene cluster is disclosed as encoding a gene cluster for the production of “tombamycin”; however, the compound and, therefore, uses of such a compound cannot be found in the prior art. As noted above, the antibiotic “tombramycin” is described in limited fashion in the prior art without disclosure of its source species (the genes described herein are from *Sorangium cellulosum* which is not disclosed as producing an antibiotic by the name of either tombamycin or tombramycin in the “Background of the Invention” on page 1 of the specification.

10. Claims 4-13 are also rejected under 35 U.S.C. § 112, first paragraph, enablement. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

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international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

11. Claims 4 and 9 are rejected under 35 U.S.C. § 102(e) as being anticipated by USPN 6090601 (see IDS). The instant claims are drawn to vectors comprising PKS-domain-portions of SEQ ID NO:12 and methods of using said vector to produce a PKS.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. § 102(e). This rejection under 35 U.S.C. § 102(e) might be overcome either by a showing under 37 C.F.R. § 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 C.F.R. § 1.131.

Gustafsson *et al.* teach SEQ ID NOs:11 and 12, disclosed as encoding polyketide synthase domains (see Claim 11); a portion of each of SEQ ID NOs: 11 and 12 is identical to a portion of SEQ ID NO:12 in the instant application (see attached alignments). Methods of expressing the encoded proteins are also taught (see Abstract).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

12. Claims 4 and 5 are rejected under the judicially created doctrine of double patenting over claim 4 of U. S. Patent No. 6,280,999 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a portion of tmbA and a portion of tmbB wherein each portion is large enough to comprise at least one PKS domain.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also M.P.E.P. § 804.

Conclusion

13. Claims 4-13 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Examiner
Art Unit 1652

August 4, 2004

ALIGNMENTS

US-09-010-809-11

; Sequence 11, Application US/09010809B
 ; Patent No. 6090601
 ; GENERAL INFORMATION:
 ; APPLICANT: Gustafsson, Claes
 ; APPLICANT: Betlach, Mary C.
 ; TITLE OF INVENTION: Epothilone Polyketide Synthases and Encoding DNA
 ; TITLE OF INVENTION: Therefor
 ; FILE REFERENCE: 30062-20020.00
 ; CURRENT APPLICATION NUMBER: US/09/010,809B
 ; CURRENT FILING DATE: 1998-01-22
 ; NUMBER OF SEQ ID NOS: 23
 ; SOFTWARE: PatentIn Ver. 2.0
 ; SEQ ID NO 11
 ; LENGTH: 787
 ; TYPE: DNA
 ; ORGANISM: Sorangium cellulosum
 ; FEATURE:
 ; OTHER INFORMATION: "n" at various positions throughout the sequence may
 ; OTHER INFORMATION: be A, T, C, G, other or unknown

US-09-010-809-11

Query Match 0.8%; Score 220; DB 3; Length 787;
 Best Local Similarity 99.4%; Pred. No. 3e-80;
 Matches 320; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

Qy (——15914 ATGCATTGCGCGCTTGGATCGAGCGGGGCGCGCCAACGCCTGTGCGGGTGGTGATCGACA 15973
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Db 1 ATGCATTGCGCGCTTGGATCGAGCGGGGCGCGCCAACGCCTGTGCGGGTGGTGATCGACA 60

Qy 15974 CGAACGCTGCCAGCTCACCGCGCTCGGACGTGGCGGGGTCGTGCGACGAGGCGACGAGGC 16033
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Db 61 CGAACGCTGCCAGCTCACCGCGCTCGGACGTGGCGGGGTCGTGCGACGAGGCGACGAGGC 120

Qy 16034 AGGCGCTGTCGCTGCTGCAAGCGTGGTTGTTCGGAGCCGCGGCTCGACGCTGTTCGAGCTGG 16093
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Db 121 AGGCGCTGTCGCTGCTGCAAGCGTGGTTGTTCGGAGCCGCGGCTCGACGCTGTTCGANCTGG 180

Qy 16094 TGTGGGTGACGCGGGGCGCGGTCAGCGCAGCTCCGGACGACGCCGTTCGAGGACCTGGCGC 16153
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Db 181 TGTGGGTGACGCGGGGCGCGGTCAGCGCAGCTCCGGACGACGCCGTTCGANGACCTGGCGC 240

Qy 16154 ACGGGCCGCTGTGGGGGCTTATTCGCACGGCGCGCAGCGAGCACCCCGAGCGCCGGCTGC 16213
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Db 241 ACGGGCCGCTGTGGGGGCTTATTCGCACGGCGCGCAGCGAGCACCCCGAGCGCCGGCTGC 300

Qy 16214 GCTTGATCGATGTGGGGACCGA 16235 — 27705
 ||||||||||||||||||||
 Db 301 GCTTGATCGATGTGGGGACCGA 322

787

US-09-010-809-12
; Sequence 12, Application US/09010809B
; Patent No. 6090601
; GENERAL INFORMATION:
; APPLICANT: Gustafsson, Claes
; APPLICANT: Betlach, Mary C.
; TITLE OF INVENTION: Epothilone Polyketide Synthases and Encoding DNA
; TITLE OF INVENTION: Therefor
; FILE REFERENCE: 30062-20020.00
; CURRENT APPLICATION NUMBER: US/09/010,809B
; CURRENT FILING DATE: 1998-01-22
; NUMBER OF SEQ ID NOS: 23
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 12
; LENGTH: 750
; TYPE: DNA
; ORGANISM: Sorangium cellulosum
; FEATURE:
; OTHER INFORMATION: "n" at various positions throughout the sequence may
; OTHER INFORMATION: be A, T, C, G, other or unknown
US-09-010-809-12

Query Match 1.3%; Score 368; DB 3; Length 750;
Best Local Similarity 100.0%; Pred. No. 1.1e-140;
Matches 368; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 18764 GGATCAGCGGGACGAACGCCCATGTCATCCTCGAAGAGGCGCCGGTGGAGGCGGCTCGCG 18823
|
Db 383 GGATCAGCGGGACGAACGCCCATGTCATCCTCGAAGAGGCGCCGGTGGAGGCGGCTCGCG 442
Qy 18824 AGCCGGTGGAGGCGGTGCGCGAGCCGGTGGAGGCGGAGGGTGTGCGATAACCGCTGTTGC 18883
|
Db 443 AGCCGGTGGAGGCGGTGCGCGAGCCGGTGGAGGCGGAGGGTGTGCGATAACCGCTGTTGC 502
Qy 18884 TGTCGGGGCGAGACGAGGCCTCGGTGGCGGCGCAGGCGGGGCGGTGGGCGAAGTGGCTGG 18943
|
Db 503 TGTCGGGGCGAGACGAGGCCTCGGTGGCGGCGCAGGCGGGGCGGTGGGCGAAGTGGCTGG 562
Qy 18944 AAGAGCACGGGGAGGTGGGGTGGTCGGACGTGGTGAGGACGGCGGCGCTGCACCGGACGC 19003
|
Db 563 AAGAGCACGGGGAGGTGGGGTGGTCGGACGTGGTGAGGACGGCGGCGCTGCACCGGACGC 622
Qy 19004 ACTTCGAGTCGCGGGCGTCGGTGCTTGCGGCGAGCGCTGCGGGAGCTGTGGAGGGTCTTC 19063
|
Db 623 ACTTCGAGTCGCGGGCGTCGGTGCTTGCGGCGAGCGCTGCGGGAGCTGTGGAGGGTCTTC 682
Qy 19064 GCGCGCTGTCGTCGGGGCGGCCGGATGCGGCGGTGGTGAGCGGGACGGCGAAGCGAGGCG 19123
|
Db 683 GCGCGCTGTCGTCGGGGCGGCCGGATGCGGCGGTGGTGAGCGGGACGGCGAAGCGAGGCG 742
Qy 19124 GGAAGCTT 19131 - 27705
|
Db 743 GGAAGCTT 750 - end